Public Health Service

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
555 Winderley Place, Suite 200
Maitland, Florida 32751

d19146

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

WARNING LETTER

FLA-98-56

June 24, 1998

Elias Salama, President
Body Fitness Products, Inc.
11100 N.W. 32nd Avenue
Miami, Florida 33167

Dear Mr. Salama:

We are writing to you because on June 2, 4 & 11, 1998, FDA Investigator Victor Spanioli collected information that revealed serious regulatory problems involving the Moulding Body, Electrical Body Belts (Class III), which are imported and distributed by your firm.

Under the Federal Food, Drug, and Cosmetic Act (The Act), these products are considered to be medical devices under section 201(h) of the Act because they are used to treat a medical condition or to affect the structure or function of the body. The law requires that manufacturers of medical devices conform with the Current Good Manufacturing Practice (CGMP) requirements of the Quality System (QS) regulation as specified in Title 21, Code of Federal Regulations (CFR), Part 820. The 1978 Good Manufacturing Practice (GMP) for Medical Devices regulation was superseded on June 1, 1997, by the Quality Systems regulation, which incorporates the device GMP.

The inspection revealed that the device is adulterated within the meaning of section 501(f)(1)(B) because it was classified under section 513(f) into class III, which under section 515(a) is required to have in effect an approved application for premarket approval, and which is not exempt from section 515 under section 520(g).

The inspection also revealed that the device is adulterated within the meaning of section 501(h) of the Act, in that the methods used in, or the facilities or controls used for the

manufacture, processing, packing, storage or distribution are not in conformance with the Current Good Manufacturing Practice (GMP) requirements of the Quality System (QS) regulation. These violations include, but are not limited to the following:

- Failure to submit Medical Device Reports (MDR) for serious injuries or reported malfunctions related to the Moulding Body device, e.g., two fires reported to you in 1997, report of a user who received second degree burns to the entire midsection of their body on October 21, 1997, fire and burns to the stomach and back of a customer reported on October 25, 1997, and numerous other reports of the Moulding Body burning or users being burned by the device (FDA 483, Item #3).

- Failure to investigate the reported complaints listed above to determine the cause of the reported injuries and device failures.

The Body Moulding device is also misbranded under section 502(o) because the device was not included in a list required by section 510(j), and a notice or other information respecting the device was not provided as required by section 510(k) of the Act, e.g., devices imported and distributed in the U.S. are required to be listed and the distributor or manufacturer must have a written order or a letter of substantial equivalence prior to commercial marketing of the device.

Further, it is your responsibility to ensure proper and accurate entries are submitted to the United States Customs Service (USCS) and the Food and Drug Administration at the time devices for medical use are presented for entry into the United States, e.g., six entries accounting for over 20,000 units beginning on July 3, 1997 with the last entry being made on May 1, 1998 were made without proper notice being given to the FDA for review prior to entry and distribution.

You should know that these are serious violations of the law that may result in FDA taking regulatory action without further notice to you. These actions include, but are not limited to, seizing your product inventory, obtaining a court injunction against further marketing of the product, or assessing civil money penalties. It is your responsibility to ensure adherence to each requirement of the Act and regulations. The specific violations noted in this letter and in the Inspectional Observations (FDA 483), issued to you at the closeout of the inspection may be symptomatic of serious underlying problems in your firm's importing and distribution and quality assurance systems. Also, other Federal agencies are informed about the warning letters we issue, such as this one, so that they may consider this information when awarding government contracts.

It is necessary for you to take action on this matter. Please let this office know in writing within 15 working days of receipt of this letter what steps you are taking to prevent this from happening again. If you need more time, let us know why and when you expect to complete your correction.

Please direct your response to Timothy J. Couzins, Compliance Officer, Food & Drug Administration, Florida District, 555 Winderley Place, Suite 200, Orlando, Florida 32751.

Finally, you should understand that there are many FDA requirements pertaining to the manufacture and marketing of medical devices. This letter pertains only to the requirements for the conformance of your devices with the Good Manufacturing Practice and the Quality System Regulations and does not necessarily address other obligations you have under the law. You may obtain general information about all of the FDA requirements for manufacturers of medical devices by contacting this office or through the Internet at http://www.fda.gov.

If you have more specific questions about the Quality System Regulation and how it affects your particular devices, or about the content of this letter, please contact Tim Couzins at (407) 475-4728.

Sincerely,

Douglas D. Tolen

Douglas D. Tolen
Director, Florida District